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ARTICLE INFO

Article history:
Accepted 22 April 2013

- **Brinkhaus B, Ortiz M, Witt CM, Roll S, Linde K, Pfab F, et al. Acupuncture in patients with seasonal allergic rhinitis: a randomized trial. *Ann Intern Med* 2013;158(4):225-34.**

Background: Acupuncture is frequently used to treat seasonal allergic rhinitis (SAR) despite limited scientific evidence.

Objective: To evaluate the effects of acupuncture in patients with SAR.

Design: Randomized, controlled multicenter trial. (ClinicalTrials.gov: NCT00610584) SETTING: 46 specialized physicians in 6 hospital clinics and 32 private outpatient clinics.

Patients: 422 persons with SAR and IgE sensitization to birch and grass pollen.

Intervention: Acupuncture plus rescue medication (RM) (cetirizine) (n = 212), sham acupuncture plus RM (n = 102), or RM alone (n = 108). Twelve treatments were provided over 8 weeks in the first year.

Measurements: Changes in the Rhinitis Quality of Life Questionnaire (RQLQ) overall score and the RM score (RMS) from baseline to weeks 7 and 8 and week 16 in the first year and week 8 in the second year after randomization, with predefined noninferiority margins of -0.5 point (RQLQ) and -1.5 points (RMS).

Results: Compared with sham acupuncture and with RM, acupuncture was associated with improvement in RQLQ score (sham vs. acupuncture mean difference, 0.5 point [97.5% CI, 0.2 to 0.8 point; $P < 0.001$]; RM vs. acupuncture mean difference, 0.7 point [97.5% CI, 0.4 to 1.0 point; $P < 0.001$]) and RMS (sham vs. acupuncture mean difference, 1.1 points [97.5% CI, 0.4 to 1.9 points; $P < 0.001$]; RM vs. acupuncture mean difference, 1.5 points [97.5% CI, 0.8 to 2.2 points; $P < 0.001$]). There were no differences after 16 weeks in the first year. After the 8-week follow-up phase in the second year, small improvements favoring real acupuncture over the sham procedure were noted (RQLQ mean difference, 0.3 point [95% CI, 0.03 to 0.6 point; $P = 0.032$]; RMS mean difference, 1.0 point [95% CI, 0.2 to 1.9 points; $P = 0.018$]).

Limitation: The study was not powered to detect rare adverse events, and the RQLQ and RMS values were low at baseline.

Conclusion: Acupuncture led to statistically significant improvements in disease-specific quality of life and antihistamine use measures after 8 weeks of treatment compared with sham acupuncture and with RM alone, but the improvements may not be clinically significant.

- **Choi SM, Park JE, Li SS, Jung H, Zi M, Kim TH et al. A multicenter, randomized, controlled trial testing the effects of acupuncture on allergic rhinitis. *Allergy* 2013;68(3):365-74.**

Background: The aim of this study was to evaluate the efficacy and safety of acupuncture in the treatment for allergic rhinitis.

Methods: This study was a multicenter, randomized, parallel-controlled study. Participants were randomized to

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2213-4220/$ – see front matter
http://dx.doi.org/10.1016/j.imr.2013.04.008

either the active acupuncture, sham acupuncture, or waitlist groups. The active and sham acupuncture groups received acupuncture treatment three times per week for 4 weeks. In the sham group, minimal acupuncture at nonacupuncture points was used. The waitlist group did not receive any acupuncture treatment.

Results: Of the 238 participants, 97, 94, and 47 individuals were assigned to the active acupuncture, sham acupuncture, and waitlist group, respectively. After the treatment, the difference in the total nasal symptom score (TNSS) was significantly reduced in the active acupuncture group compared with the sham acupuncture (difference: -1.03, 95% confidence interval [CI]: -1.96, -0.09, P = 0.03) and waitlist (difference: -2.49, 95% CI: -3.68, -1.29, P < 0.0001). The active acupuncture group exhibited a significant change in the total non-nasal symptom score (TNNSS) compared with the waitlist (difference: -0.78, 95% CI: -1.22, -0.34, P = 0.0002), but not the sham acupuncture group (difference; 0.15, 95% CI: -0.21, 0.5, P = 0.56). Both active and sham acupuncture treatments resulted in significant improvements in TNSS and TNNSS compared to baseline.

Conclusion: Active acupuncture showed a significantly greater effect on symptoms of allergic rhinitis than either sham acupuncture or no active treatment. The symptoms of allergic rhinitis decreased significantly after treatment in the both acupuncture and sham acupuncture groups. Acupuncture appears to be an effective and safe treatment for allergic rhinitis.

- **Chae Y, Chang DS, Lee SH, Jung WM, Lee IS, Jackson S, et al. Inserting needles into the body: a meta-analysis of brain activity associated with acupuncture needle stimulation. *J Pain* 2013;14(3):215-22.**

Acupuncture is a therapeutic treatment that is defined as the insertion of needles into the body at specific points (ie, acupoints). Advances in functional neuroimaging have made it possible to study brain responses to acupuncture; however, previous studies have mainly concentrated on acupoint specificity. We wanted to focus on the functional brain responses that occur because of needle insertion into the body. An activation likelihood estimation meta-analysis was carried out to investigate common characteristics of brain responses to acupuncture needle stimulation compared to tactile stimulation. A total of 28 functional magnetic resonance imaging studies, which consisted of 51 acupuncture and 10 tactile stimulation experiments, were selected for the meta-analysis. Following acupuncture needle stimulation, activation in the sensorimotor cortical network, including the insula, thalamus, anterior cingulate cortex, and primary and secondary somatosensory cortices, and deactivation in the limbic-paralimbic neocortical network, including the medial prefrontal cortex, caudate, amygdala, posterior cingulate cortex, and parahippocampus, were detected and assessed. Following control tactile stimulation, weaker patterns of brain responses were detected in areas similar to those stated above. The activation and deactivation patterns following acupuncture stimulation suggest that the hemodynamic responses in the brain simultaneously reflect the sensory, cognitive, and affective dimensions of pain. PERSPECTIVE: This article facilitates a better understanding of acupuncture needle stimulation and its effects on specific activity changes in different brain regions as well as its relationship to the multiple dimensions of pain. Future studies can build on this meta-analysis and will help to elucidate the clinically relevant therapeutic effects of acupuncture.

- **Vickers AJ, Cronin AM, Maschino AC, Lewith G, MacPherson H, Foster NE, et al. Acupuncture for chronic pain: individual patient data meta-analysis. *Arch Intern Med* 2012;172(19):1444-53.**

Background: Although acupuncture is widely used for chronic pain, there remains considerable controversy as to its value. We aimed to determine the effect size of acupuncture for 4 chronic pain conditions: back and neck pain, osteoarthritis, chronic headache, and shoulder pain.

Methods: We conducted a systematic review to identify randomized controlled trials (RCTs) of acupuncture for chronic pain in which allocation concealment was determined unambiguously to be adequate. Individual patient data meta-analyses were conducted using data from 29 of 31 eligible RCTs, with a total of 17 922 patients analyzed.

Results: In the primary analysis, including all eligible RCTs, acupuncture was superior to both sham and no-acupuncture control for each pain condition (P < .001 for all comparisons). After exclusion of an outlying set of RCTs that strongly favored acupuncture, the effect sizes were similar across pain conditions. Patients receiving acupuncture had less pain, with scores that were 0.23 (95% CI, 0.13-0.33), 0.16 (95% CI, 0.07-0.25), and 0.15 (95% CI, 0.07-0.24) SDs lower than sham controls for back and neck pain, osteoarthritis, and chronic headache, respectively; the effect sizes in comparison to no-acupuncture controls were 0.55 (95% CI, 0.51-0.58), 0.57 (95% CI, 0.50-0.64), and 0.42 (95% CI, 0.37-0.46) SDs. These results were robust to a variety of sensitivity analyses, including those related to publication bias.

Conclusions: Acupuncture is effective for the treatment of chronic pain and is therefore a reasonable referral option. Significant differences between true and sham acupuncture indicate that acupuncture is more than a placebo. However, these differences are relatively modest, suggesting that factors in addition to the specific effects of needling are important contributors to the therapeutic effects of acupuncture.

- **Shah GR, Chaudhari MV, Patankar SB, Pensalwar SV, Sabale VP, Sonawane NA. Evaluation of a multi-herb supplement for erectile dysfunction: a randomized double-blind, placebo-controlled study. *BMC Complement Altern Med* 2012;12:155.**

Backgroud: Evidence is lacking for multi-ingredient herbal supplements claiming therapeutic effect in sexual

dysfunction in men. We examined the safety and efficacy of VigRX Plus (VXP) - a proprietary polyherbal preparation for improving male sexual function, in a double blind, randomized placebo-controlled, parallel groups, multi-centre study.

Methods: 78 men aged 25-50 years of age; suffering from mild to moderate erectile dysfunction (ED), participated in this study. Subjects were randomized to receive VXP or placebo at a dose of two capsules twice daily for 12 weeks. The international index of erectile function (IIEF) was the primary outcome measure of efficacy. Other efficacy measures were: Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS), Serum testosterone, Semen analysis, Investigator's Global assessment and Subjects' opinion.

Results: In subjects receiving VXP, the IIEF-Erectile Function (EF) scores improved significantly as compared to placebo. After 12 weeks of treatment, the mean (sd) IIEF-EF score at baseline increased from 16.08 (2.87) to 25.08 (4.56) in the VXP group versus 15.86 (3.24) to 16.47 (4.25) in the placebo group ($P < 0.0001$). Similar results were observed in each of the remaining four domains of the IIEF (orgasmic function, sexual desire, intercourse satisfaction, and overall satisfaction).There was a significant difference for VXP versus placebo comparison of mean (sd) EDITS scores of patients: 82.31(20.23) vs 36.78(22.53) and partners:(82.75(9.8) vs 18.50(9.44);$P < 0.001$. Thirty-five out of 39 (90%) subjects from the VXP group and one (3%) from the placebo group wished to continue with the treatment they received. Investigator's global assessment rated VXP therapy as very good to excellent in more than 50% patients and placebo therapy as fair to good in about 25% of patients. Incidence of side effects and subject's rating for tolerability of treatment was similar in both groups.

Conclusions: VigRX Plus was well tolerated and more effective than placebo in improving sexual function in men.

- **Lee NH, Yoo SR, Kim HG, Cho JH, Son CG. Safety and tolerability of Panax ginseng root extract: a randomized, placebo-controlled, clinical trial in healthy Korean volunteers. *J Altern Complement Med* 2012;18(11):1061-9.**

Objectives: Panax ginseng has been extensively used as an adaptogen and is among the top 10 selling herbal supplements in the United States over the past decade. However, there have been few reports about the toxicity of P. ginseng in human studies. Given the lack of toxicological studies in human, this study investigated whether P. ginseng administration causes any noticeable toxic effects in healthy volunteers.

Methods: This study was designed as a randomized, double-blind, placebo-controlled, and parallel group trial in healthy volunteers. The subjects were required to be healthy, free from any significant disease, as assessed at screening by physical examination, medical history, and laboratory (hematological and biochemical) tests. Eligible subjects received P. ginseng extract (1 g/day or 2 g/day) or placebo over a 4-week period.

Results: Although mild adverse events, such as dyspepsia, hot flash, insomnia, and constipation, were reported in both P. ginseng and placebo group, no serious untoward reactions were reported following P. ginseng administration. Nonsignificant changes were observed in hematological and biochemical tests.

Conclusions: P. ginseng administration for 4 weeks was shown to be safe, tolerable, and free of any untoward toxic effect in healthy male and female volunteers. Future results from ongoing multicenter collaborative efforts to evaluate short- and long-term effects of P. ginseng may contribute to our current understanding of safety and tolerability of this herbal product.

- **Schmid AA, Van Puymbroeck M, Altenburger PA, Schalk NL, Dierks TA, Miller KK, et al. Poststroke balance improves with yoga: a pilot study. *Stroke* 2012;43(9):2402-7**

Background and purpose: Balance impairment is common after stroke; modified yoga may be able to improve balance and other important poststroke variables. Scientific-evidence is needed to support such treatment interventions. The purpose of this study was to assess the impact of a yoga-based rehabilitation intervention on balance, balance self-efficacy, fear of falling (FoF), and quality of life after stroke.

Methods: This was a prospective, randomized, pilot study of yoga-based rehabilitation for people with chronic stroke. All yoga sessions were taught by a registered yoga therapist, occurred twice per week for 8 weeks and included seated, standing, and floor postures with relaxation and meditation. Balance was assessed with the Berg Balance Scale, balance self-efficacy with the Activities-specific Balance Confidence Scale, FoF with a dichotomous yes/no question, and quality of life with the Stroke Specific Quality of Life scale.

Results: There were no significant differences between wait-list control ($n = 10$) and yoga ($n = 37$) groups in baseline or follow-up scores. However, using within-group comparisons, yoga group data demonstrated significant improvement in balance (Berg Balance Scale, 41.3 ± 11.7 vs 46.3 ± 9.1; $P < 0.001$) and FoF (51% vs 46% with FoF; $P < 0.001$).

Conclusions: A group yoga-based rehabilitation intervention for people with chronic stroke has potential in improving multiple poststroke variables. Group yoga may be complementary to rehabilitation, may be possible in medical-based and community-based settings, and may be cost-effective. Further testing of group yoga-based rehabilitation interventions is warranted. Clinical Trial Registration- URL: http://clinicaltrials.gov. Unique Identifier: NCT01109602.